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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,067	07/03/2003	David Lewis	239770US0DIV	3508

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/612,067	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendments and Remarks filed on 11/27/06 and a new IDS filed on 12/29/06. Claims 24, 28, 32-33, 39, 41-42 and 44-45 have been amended and new claims 46-48 have been added, while no claims have been cancelled. Accordingly claims 24-48 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 27, 30-32, 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Porush et al (2,868,691).

Porush et al disclose self-propelling compositions for inhalation therapy. The formulations which are in a stable solution form comprise one or more active agents such as vasoconstrictive amines, **steroids**, bronchodilators, analgesics, etc. The said formulations also comprise **propellants**, stabilizers and solvents (col. 2, lines 41-55). Propellant is either a fluorinated or flurochlorinated hydrocarbon (col. 2, lines 1-12). Preferred solvents and co-solvents are lower alcohols such as ethanol, diethyl ether, etc. A mixture of **ethanol** and water is also suitable (see col. 2, line 61 to col. 3, line 7). Preferred stabilizers are **anti-oxidants** such as sodium ascorbate, ascorbic acid,

butylated hydroxytoluene, etc. The stabilizer is employed in an amount of 0.25% or less by weight of the composition (see col. 3, lines 8-17).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28, 29, 33-34 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Tzou et al (5,776,433).

Porush et al, discussed above, lacks disclosure on specific steroids such as flunisolide or beclomethasone dipropionate.

Tzou teaches **flunisolide** aerosol formulations comprising a therapeutically effective amount of flunisolide in **solution** with **ethanol** and a **propellant** selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof used for the treatment of bronchial asthma. The formulations may be delivered by a metered dose inhaler with a canister that is inert to flunisolide (see abstract). Tzou discloses that NASALIDE® nasal solution comprises excipients such as butylated hydroxyanisole (col. 1, lines 17-26). It is also disclosed that in the formulations of the invention, the flunisolide is fully dissolved and the formulation is free from undissolved flunisolide (col. 2, lines 36-40). Aerosol canisters equipped with conventional valves, preferably metered dose valves (col. 3, lines 45-50).

It would have been obvious to one of ordinary skill in the art to have combined the formulations of Porush et al on solutions of steroids comprising solvents, propellants and antioxidants for inhalation therapy with the formulations as taught by Tzou et al on flunisolide solution formulations comprising antioxidants, specific propellants and solvents for administration to the pulmonary system for treating bronchial disorders with reasonable expectations of successfully preparing a stable solution formulation for direct delivery to patients to treat respiratory disorders. In other words the combination of references provide one of ordinary skill in the art with sufficient information to make and use the instant invention.

Claims 25-26, 37-38 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Rubin (4,584,320).

Porush et al, discussed above, lacks disclosure on specific antioxidants and the higher concentration ranges of the anti-oxidants.

Rubin teaches anti-asthmatic compositions for oral or nasal administration. The said formulations comprise an active agent, a suitable **propellant** and excipients. Since the active agents are subject to oxidation, **antioxidants** should be added. Suitable antioxidants include **butylated hydroxytoluene**, butylated hydroxyanisole, ascorbic acid, **ascorbyl palmitate, tocopherol** etc (col. 3, lines 38-53 and claim 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Porush et al to have looked in the art for other specific antioxidants suitable for inhalation preparations such as tocopherol and ascorbyl palmitate, with the reasonable expectations of successfully preparing a stable and efficient formulation for treating respiratory disorders. Rubin's disclosure of butylated hydroxytoluene, butylated hydroxyanisole, ascorbic acid, ascorbyl palmitate and tocopherol as suitable antioxidants also suggests that the said antioxidants are art recognized equivalents and that one of ordinary skill in the art would have been able to substitute one for another without undue experimentation. Furthermore, although neither art references teaches using antioxidants in an amount of 1 to 2%, it is the Examiner's position that optimization of ranges is a routine practice and not support for patentability. In other words formulations comprising 1 or 2% antioxidants are not patentably distinguished over prior art's formulations comprising 0.25% antioxidants.

Response to Arguments

Applicant's arguments with respect to claims 24-45 have been considered but are moot in view of the new ground(s) of rejection.

However Applicant's arguments with regard to Rubin is briefly responded to since this prior art reference is still deemed applicable as a supporting art.

Applicant argues that Rubin's formulations are suspensions and they do not contain solvents. This is not persuasive because Rubin was brought in as a supportive prior art of reference merely to show that antioxidants are recognized in the art as being

equivalents and one of ordinary skill in the art would have been able to selecet any one of the said antioxidants for a formulation, whether a solution or a suspension. In other words, the same antioxidants would perform their function in any formulation. Also there is no criticality shown in using a specific antioxidants in a solution formulation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
02/16/07

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